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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,113	10/23/2001	Eric K. Engelhard	A-70970/RMS/DCF	3901

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/004,113

**Applicant(s)**

ENGELHARD ET AL.

**Examiner**

Alana M. Harris, Ph.D.

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C.

121:

1-60. Claims 1-4, drawn to a recombinant nucleic acid listed in Tables 1-10 consisting of sequences, SEQ ID NO: 1-60 and the expression vector and host cell, which the said nucleic acid is contained, respectively, classified in class 536, subclass 23.5.

61-120. Claim 5, drawn to a recombinant protein encoded by one of the sixty sequences listed in Tables 1-10, respectively, classified in class 530, subclass 350.

121-180. Claims 6 and 7, drawn to a method of screening drug candidates comprising providing a cell that expresses a carcinoma associated (CA) gene comprising a nucleic acid sequence (SEQ ID NO: 1-60) outlined in Tables 1-10 and adding a drug candidate to said cell and determining the level of CA gene expression, respectively, classified in class 435, subclass 6.

181-240. Claims 8 and 9, drawn to a method of screening for a bioactive agent capable of binding and modulating the activity of an CA protein (CAP) encoded by one of SEQ ID NO: 1-60 comprising combining said CAP and a candidate bioactive agent and determining bioactivity of said CAP, respectively, classified in class 435, subclass 7.1.

- 241-300. Claims 10 and 11, drawn to a method of evaluating the effect of a candidate carcinoma drug comprising administering said drug to a patient, removing a cell sample and determining alterations in the expression or activation of a gene comprising a nucleic acid sequence consisting of a sequence outlined in Tables 1-10, respectively, classified in class 436, subclass 63.
- 301-360. Claim 12, drawn to a method for inhibiting the activity of a CAP encoded by a nucleic acid sequence outlined in Tables 1-10, respectively, classified in class 435, subclass 7.1.
- 361-420. Claims 13 and 14, drawn to a method of treating carcinomas comprising administering to a patient an inhibitor of an CAP, wherein the CAP is encoded by a nucleic acid sequence (SEQ ID NO: 1-60) outlined in Tables 1-10, respectively, classified in class 424, subclass 130.1.
- 421-480. Claims 15 and 16, drawn to an antibody, which specifically binds to a protein encoded by a nucleic acid (SEQ ID NO: 1-60), respectively, classified in class 530, subclass 387.1.
- 481-540. Claim 17, drawn to a biochip comprising one or more nucleic acid segments selected from the group consisting of a nucleic acid of the sequences outlined in Tables 1-10, respectively, classified in class 536, subclass 23.1.

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541-600. Claim 18, drawn to a method of diagnosing carcinoma by sequencing at least CA gene, which may be SEQ ID NO: 1-60, respectively, classified in class 536, subclass 174.

601-660. Claim 19, drawn to a method of determining CA gene copy number comprising adding an CA gene probe comprising a sequence of SEQ ID NO: 1-60 to a sample of genomic DNA from an individual and implementing hybridization, respectively, classified in class 435, subclass 7.92.

2. The inventions are distinct, each from the other because of the following reasons:

Groups 1-120 and 421-540 are structurally and functionally different products, which are made by different methods and have different uses.

The methods of Groups 121-420 and 541-660 differ in the method objectives, method steps and parameters and in the reagents used.

The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions 121-240, 301-360, 541-660 and 241-300, 361-420 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the *in vitro* methods of Inventions 121-240, 301-360, 541-660 and distinct

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and from the *in vivo* methods of Inventions 241-300, 361-420 and are not useable nor searchable together.

Inventions 481-540 are related to Groups 541-660 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the biochip products of Group 481-540 could be used in any of the methods of Groups 541-660.

Inventions 121-300, 361-420 are unrelated to Inventions 481-540. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of 121-300, 361-420 cannot use the biochips of the Groups 481-540 designated as Invention VIII, thus not useable nor searchable together.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. A telephone call was made to Shantanu Basu on March 30, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

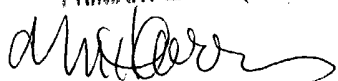
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however can generally be reached between the hours of 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
30 March 2004